

**[0011]** One significant limitation besetting bladder reconstruction is directly related to the availability of donor tissue. The limited availability of bladder tissue prohibits the frequent routine reconstruction of bladder using normal bladder tissue. The bladder tissue that is available, and considered usable, may itself include inherent imperfections and disease. For example, in a patient suffering from bladder cancer, the remaining bladder tissue may be contaminated with metastasis. Accordingly, the patient is predestined to less than perfect bladder function.

**[0012]** Accordingly, there exists a need for methods and devices for the reconstruction, repair, augmentation or replacement of organs or tissue structures in a patient in need of such treatment. In addition, there is a need for artificial organ constructs with improved biomechanical properties.

#### BRIEF SUMMARY OF THE INVENTION

**[0013]** Biocompatible synthetic or natural scaffolds are provided for the reconstruction, repair, augmentation or replacement of organs or tissue structures in a patient in need of such treatment.

**[0014]** The scaffolds are shaped to conform to at least a part of the organ or tissue structure and may be seeded with one or more cell populations. The seeded scaffolds are implanted into the patient at the site in need of treatment to form an organized organ or tissue structure. The scaffolds may be used to form organs or tissues, such as a bladder.

**[0015]** The constructs described herein for the reconstruction, repair, augmentation or replacement of laminarily organized luminal organs or tissue structures include an implantable, biocompatible, synthetic or natural polymeric matrix or scaffold having at least two separate surfaces and shaped to conform to at least a part of the luminal organ or tissue structure in need of the treatment, at least one receptacle or port adapted to receive a tubular vessel or insert; and at least one cell population deposited on or in a first surface of the polymeric matrix, a second surface of the polymeric matrix, or both, to form a construct of matrix plus cells, wherein the at least one cell population comprises at least one cell population that is substantially a muscle cell population. The muscle cell population is, e.g., a smooth muscle cell population. Optionally, a second cell population may be deposited on or in a first surface of the polymeric matrix, a second surface of the polymeric matrix, or both, wherein the second cell population comprises a urothelial cell population.

**[0016]** The constructs described herein for the reconstruction, repair, augmentation or replacement of laminarily organized luminal organs or tissue structures also comprise a first implantable, biocompatible, synthetic or natural polymeric matrix or scaffold having at least two separate surfaces, and a second implantable, biocompatible, synthetic or natural polymeric matrix or scaffold having at least two separate surfaces, which are adapted to mate to each other and shaped to conform to at least a part of the luminal organ or tissue structure in need of the treatment when mated. The first and second polymeric matrices may be formed from one integral unit subdivided into two or more distinct parts, or from two or more distinct parts, adapted to mate.

**[0017]** In some embodiments, the first and second polymeric matrices are symmetrical, while in other embodiments, the first and second polymeric matrices are asymmetrical. In one embodiment, the first polymeric matrix or scaffold has a hemispherical or quasi-hemispherical shape having a closed, domed end and an open, equatorial border, and the second

polymeric matrix or scaffold is a collar adapted to mate with the equatorial border of the first polymeric matrix. In another embodiment, the first and second polymeric matrices are each hemispherical or quasi-hemispherical in shape, having a closed, domed end and an open, equatorial border. In yet another embodiment, the first and second polymeric matrices each comprise a circular or semi-circular base and at least 2 petals radially extending from each base. In this embodiment, the bases and petal shaped portions of the first and the second polymeric matrices are mated to create a hollow spherical or quasi-spherical matrix or scaffold such that a flanged longitudinal, elliptical opening is created on one side of the mated polymeric matrices, and a circular opening is created on the side opposite the longitudinal opening. In another embodiment, the first and second polymeric matrices are made from 3 parts comprising a top, a front and a sidepiece, adapted to mate. In this embodiment, the 3 distinct parts are mated using at least 3, preferably four vertical seams, thereby forming a crown shaped neo-bladder construct. The crown shaped constructs are preferably used alone as a device for organ repair or augmentation.

**[0018]** The first polymeric matrix or the second polymeric matrix, if any, or both, comprise at least one cell population deposited on or in a first surface of the first polymeric matrix, a first surface of the second polymeric matrix, or both, to form a construct of matrix or scaffold plus cells, wherein at least one cell population comprises substantially a muscle cell population. The muscle cell population is, e.g., a smooth muscle cell population. Optionally, a second cell population may be deposited on or in a second surface of the first polymeric matrix or a second surface of the second polymeric matrix, or both, wherein the second cell population comprises a urothelial cell population. Additionally, the first polymeric matrix, the second polymeric matrix, or both, may contain at least one receptacle or port adapted to receive a tubular vessel or insert where the connection of the construct to a native vessel or tube is necessary.

**[0019]** The biocompatible material used for these constructs is, for example, biodegradable. In some constructs, the biocompatible material is polyglycolic acid. The vessels or inserts are themselves, for example, cylindrical or tubular shaped polymer matrices, each having at least one flange located at a first end of the cylindrical polymer. The vessels or inserts are, preferably, composed of the same biocompatible material as the first or second polymeric matrices described above. In some embodiments, the vessel or insert also contains a washer adapted to fit around the cylindrical or tubular vessel or insert polymer matrix. For example, the washer is a hydrogel. The cylindrical or tubular vessel or insert may optionally contain a washer. The washer may be hydrogel. Additionally, the cylindrical or tubular insert may be self-stabilizing.

**[0020]** These constructs are used to treat, repair, augment or replace luminal organ or tissue structures such as genitourinary organs, including for example, the urinary bladder, ureters and urethra. For example, the luminal organ or tissue structure is a bladder or bladder segment, and the polymeric matrix or scaffold has smooth muscle cells deposited on a surface of the matrix.

**[0021]** In one embodiment, the methods described herein for the reconstruction, repair, augmentation or replacement of laminarily organized luminal organs or tissue structures in a patient in need of such treatment include the following steps: providing a biocompatible synthetic or natural polymeric